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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/496,391      | 02/02/2000  | James D. San Antonio | SAN01-NP001         | 6140             |

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[REDACTED] EXAMINER

CANELLA, KAREN A

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1642

DATE MAILED: 04/23/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                                      |                                          |                                                                                     |
|--------------------------------------|------------------------------------------|-------------------------------------------------------------------------------------|
| Application No.<br><b>09/496,391</b> | Applicant(s)<br><b>San Antonio et al</b> |  |
| Examiner<br><b>Karen Canella</b>     | Art Unit<br><b>1642</b>                  |                                                                                     |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4)  Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-75 are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |                                                                                               |                                                                             |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

1. Acknowledgment is made of applicant's election with traverse of Group I and the peptide motif of XBBBXXBX. Upon review and reconsideration, and in consideration of applicant's arguments, the Restriction requirement of Paper No. 11 is withdrawn. The following Restriction is required.

### *Election/Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1, 3 in part, 4, 6 in part, 7, 9 in part, 68 in part and 69 in part, drawn to synthetic peptides comprising the motif of XBBBXXBX and XBXXXBBBX, classified in class 530, subclass 300. Claims 3, 6, 9, 68 and 69 will be examined with this group to the extent that they read on the peptide motifs of XBBBXXBX and XBXXXBBBX
  - II. Claims 2, 3 in part, 5, 6 in part, 8, 9 in part, 64, 66, 68 in part and 69 in part, drawn to synthetic peptide comprising the motif of XBBXBX and XBXB BX, classified in class 530, subclass 300. Claims 3, 6, 9, 68 and 69 will be examined with this group to the extent that they read on the peptide motifs of XBBXBX and XBXB BX.
  - III. Claims 16, 34 in part, and 43, drawn to methods of affinity purification using the synthetic peptides of Group I, classified in class 530, subclass 413. Claim 34 will be examined with this group to the extent that it reads on the peptide motifs of XBBBXXBX and XBXXXBBBX
  - IV. Claims 25, 34 in part, and 61 in part, drawn to methods of affinity purification using the synthetic peptides of Group II, classified in class 530, subclass 413. Claims 34 and 61 will be examined with this group to the extent that they read on the peptide motifs of XBBXBX and XBXB BX.

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- V. Claims 14, 32 in part, 41, and 59 in part, drawn to methods of targeting drugs in a mammal comprising the administration of the peptides of Group I, classified, for example, in class 514 subclasses 2 and 34. Claims 32 and 59 will be examined with this group to the extent that they read on the peptide motifs of XBBBXXBX and XBXXXBBX
- VI. Claims 23, 32 in part, 50 and 59 in part, drawn to methods of targeting drugs in a mammal comprising the administration of the peptides of Group II, classified, for example, in class 514, subclasses 2 and 34. Claims 32 and 59 will be examined with this group to the extent that they read on the peptide motifs of XBBXBX and XBXB BX.
- VII. Claims 12, 30 in part, 39 and 57 in part, drawn to methods of modulating tumor cell metastasis comprising the administration of the peptides of Group I, classified in class 514, subclass 2. Claims 30 and 57 will be examined with this group to the extent that they read on the peptide motifs of XBBBXXBX and XBXXXBBX.
- VIII. Claims 21, 30 in part, 48 and 57 in part, drawn to methods of modulating tumor cell metastasis comprising the administration of the peptides of Group II, classified in class 514, subclass 2. Claims 30 and 57 will be examined with this group to the extent that they read on the peptide motifs of XBBXBX and XBXB BX.
- IX. Claims 10, 11, 13, 15, 17, 18, 28 in part, 29 in part, 31 in part, 33 in part, 35 in part, 36 in part, 37, 38, 40, 42, 44, 45, 55 in part, 56 in part, 58 in part, 60 in part, 62 in part, 63 in part, 70, 72 in part, 73, and 75 in part, drawn to methods of modulating glycosaminoglycans with anti-coagulant activity, methods of modulating enzymes that act on glycosaminoglycans, methods of blocking tissue uptake and clearance of heparin, methods of promoting wound healing, methods of promoting cell attachment or adhesion and methods for modulating endothelial cell pro-coagulant or anti-coagulant functions, all methods comprising the

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administration of the peptides of group I, classified in class 514, subclass 2.

Claims 28, 29, 31, 33, 35, 36, 55, 56, 58, 60, 62, 63, 72, and 75 will be examined with this group to the extent that it reads on the peptide motifs of XBBBXXBX and XBXXXBBBX

- X. Claims 19, 20, 22, 24, 26, 27, 28 in part, 29 in part, 31 in part , 33 in part, 35 in part, 36 in part, 46, 47, 49, 51-54, 55 in part, 56 in part, 58 in part, 60 in part, 62 in part, 63 in part, 71, 72 in part, 74 and 75 in part, drawn to methods of modulating glycosaminoglycans with anti-coagulant activity, methods of modulating enzymes that act on glycosaminoglycans, methods of blocking tissue uptake and clearance of heparin, methods of promoting wound healing, methods of promoting cell attachment or adhesion and methods for modulating endothelial cell pro-coagulant or anti-coagulant functions, all methods comprising the administration of the peptides of Group II, classified in class 514 subclass 2.
- Claims 28, 29, 31, 33, 35, 36, 55, 56, 58, 60, 62, 63, 72, and 75 will be examined with this group to the extent that it reads on the peptide motifs of XBBXBX and XBXXBX.
- XI. Claims 65 and 67, drawn to the peptide of SEQ ID NO:10, classified in class 530, subclass 300.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II and XI are structurally different products comprising different amino acid sequences. It is noted that SEQ ID NO:10 does not have any of the motifs required for Groups I and II: SEQ ID NO:10 has no lysine, therefore to satisfy the requirements of groups I or II it must have either two or three consecutive arginine residues, as both groups define B as arginine or lysine. An inspection of SEQ ID NO:10 indicates that this is not the case therefore, SEQ ID NO:10 is not a member of either group of peptides. Accordingly, the search for the

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peptides of Group I would not be coextensive with the search for the peptides of Group II or Group XI due to the different sequences included in each group. Therefore, the examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups III to X differ in the method objectives, method steps and parameters and in the reagents used.

Invention I is related to inventions III, V, VII and IX as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in all the processes of Groups III, V, VII and IX, in addition to being used in a process of raising an antibody.

Invention II is related to inventions IV, VI, VIII and X as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II can be used in all the processes of Groups III, V, VII and IX, in addition to being used in a process of raising an antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

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4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 22, 2003